DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 2, 2015

Medtronic, Inc.
c/o Elaine Gullane
Senior Regulatory Affairs Specialist, Medtronic Ireland
Parkmore Business Park West
Galway, Ireland

Re: K143480
Trade/Device Name: Euphora Rapid Exchange Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.5100
Regulation Name: Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter
Regulatory Class: Class II
Dated: February 17, 2015
Received: February 19, 2015

Dear Ms. Elaine Gullane:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram Zuckerman, M.D.
Director, Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143480

Device Name
Euphora™ Rapid Exchange Balloon Dilatation Catheter

Indications for Use *(Describe)*
The balloon dilatation catheter is indicated for balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion.
The balloon dilatation catheter (balloon models 2.00 mm to 4.00 mm) is also indicated for post deployment expansion of balloon expandable stents.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary per 21 CRF 807.92

Date Prepared: December 4th, 2014

Applicant:
Medtronic Ireland
Parkmore Business Park West
Galway
Ireland

Official Correspondent:
Elaine Gullane
Senior Regulatory Affairs Specialist
Medtronic Ireland
Parkmore Business Park West
Galway
Ireland
Phone: (353) 91 708682
Fax: (353) 91 708672
Email: elaine.gullane@medtronic.com

Proprietary Name: Euphora™ Rapid Exchange Balloon Dilatation Catheter

Common Name: Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter

Device Classification: Class II (special controls)

Regulation Number: 21 CFR 870.5100

Classification Name: Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter

Product Code: LOX

Device Description:

The Euphora™ RX Balloon Dilatation catheter is a Percutaneous Transluminal Coronary Angioplasty (PTCA) Rapid Exchange System. The balloon at the distal end of the catheter can be inflated to a defined diameter at a specific pressure as defined in the product labelling. The proximal end of the catheter has a female luer for attachment to an inflation device. The catheter provides a lumen which enables the use of a guidewire to position the catheter. Radiopaque balloon marker bands enable accurate placement. Shaft markers for brachial and femoral techniques are in place.

- The Euphora device is available in the following model numbers:

Diameters (mm)	Lengths (mm)						
	6	10	12	15	20	25	30
1.50	EUP1506X	EUP1510X	EUP1512X	EUP1515X	EUP1520X	-	-
2.00	EUP2006X	EUP2010X	EUP2012X	EUP2015X	EUP2020X	EUP2025X	EUP2030X
2.25	EUP22506X	EUP22510X	EUP22512X	EUP22515X	EUP22520X	EUP22525X	-
2.50	EUP2506X	EUP2510X	EUP2512X	EUP2515X	EUP2520X	EUP2525X	EUP2530X
2.75	EUP27506X	EUP27510X	EUP27512X	EUP27515X	EUP27520X	EUP27525X	-
3.00	EUP3006X	EUP3010X	EUP3012X	EUP3015X	EUP3020X	EUP3025X	EUP3030X
3.25	EUP32506X	EUP32510X	EUP32512X	EUP32515X	EUP32520X	EUP32525X	-
3.50	EUP3506X	EUP3510X	EUP3512X	EUP3515X	EUP3520X	EUP3525X	EUP3530X
3.75	EUP37506X	EUP37510X	EUP37512X	EUP37515X	EUP37520X	EUP37525X	-
4.00	EUP4006X	EUP4010X	EUP4012X	EUP4015X	EUP4020X	EUP4025X	EUP4030X

The models differ only in the balloon diameter and the balloon length across the size matrix.

- The Euphora device has a nominal pressure of 8atm and a rated burst pressure of 14atm.
- The Euphora device is single use, sterile, EtO sterilised device. It has a hydrophilic coating and is classified as an external communicating device with limited exposure i.e. whose contact with circulating blood is ≤ 24 hours.
- The Euphora device environment of use is a healthcare facility.

Indications For Use:

The Euphora™ RX Balloon Dilatation catheter is indicated for balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion. The balloon dilatation catheter (balloon models 2.00mm to 4.00mm) is also indicated for post deployment expansion of balloon expandable stents.

Substantially Equivalent Device:

The Euphora™ RX Balloon Dilatation Catheter is similar to the following predicate device with respect to intended use, design and technology:

Medtronic Sprinter Legend® RX Balloon Dilatation Catheter (P790017/S096, approved October 31, 2008)

This predicate has not been subject to a design-related recall. Reference devices were used in this submission.

Summary of Technological Differences to the Predicate Device:

The Euphora™ RX Balloon Dilatation Catheter is offered in more balloon sizes compared to its predicate and the 2.0mm diameter size is indicated for post deployment expansion of balloon expandable stents. The Euphora™ RX Balloon Dilatation Catheter has a consistent nominal (8atm) and rated burst pressure (14atm) across all balloon diameters, and has a higher nominal and rated burst pressure for the 1.5mm balloon diameter when compared to the predicate Sprinter Legend® RX Balloon Dilatation Catheter. The Euphora™ RX Balloon Dilatation Catheter incorporates the identical balloon material, identical radiopaque marker band material, identical hydrophilic coating and identical outer shaft material to the predicate device. All other materials utilized are deemed substantially equivalent to the predicate device Sprinter Legend® RX Balloon Dilatation Catheter.

Summary of Non-Clinical Data:

Design Verification in-vitro testing:

The following in-vitro bench tests were completed on the Euphora™ RX Balloon Dilatation Catheter in accordance with the requirements of *Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters, September 8, 2010* and verify that it meets the required performance specifications:

- Effective length
- Catheter Profile
- System Pressure Capability & System Pressure Capability (in Stent)
- Balloon Fatigue & Balloon Fatigue (in Stent)
- Balloon Compliance
- Balloon Inflation and Deflation Time
- Catheter Bond Strength
- Coating Integrity
- Coating Particulate Evaluation
- Flexibility and Kink
- Torque Strength

Pre-Clinical Study (non-GLP):

Medtronic conducted pre-clinical in-vivo (non-GLP) studies for evaluation of the Radiopacity attribute of the Euphora™ RX Balloon Dilatation

Catheter.

Biocompatibility Testing:

Biocompatibility testing for the Euphora™ RX Balloon Dilatation Catheter has been completed in accordance with the recommendations of *Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters, September 8, 2010* and International Standard ISO10993-1:2009, *Biological Evaluation of Medical devices- Part 1: Evaluation and Testing* for an external communicating device with limited exposure i.e. whose contact with circulating blood is ≤ 24 hours.

The following Biocompatibility tests were performed to support the Euphora™ RX Balloon Dilatation Catheter:

- Cytotoxicity Study using ISO MEM Elution method
- ISO Maximisation Sensitisation Study
- ISO Acute Intracutaneous Reactivity
- ISO Acute Systemic Toxicity
- USP Material Mediated Pyrogen Study in Rabbits
- In Vivo Thromboresistance Study
- ASTM In-vitro Haemolysis
- ASTM Partial Thromboplastin Time (PTT) Coagulation Testing
- C3a Complement Activation Assay Study
- Sc5b-9 Complement Activation Assay Study
- USP Physicochemical Tests

The Euphora™ RX Balloon Dilatation Catheter met all specified design and performance requirements. No new safety or effectiveness issues were raised during the testing. The bench testing qualification and biocompatibility testing demonstrated that the subject device Euphora™ RX Balloon Dilatation Catheter is substantially equivalent in terms of safety and effectiveness to the predicate device.

Summary of Clinical Data:

No clinical investigation has been performed for this device.

Sterilization Validation: The Euphora™ RX Balloon Dilatation Catheter will be sterilized and validated for EtO sterilization in accordance with ISO11135 and EN556 to achieve a minimum Sterility Assurance Level (SAL) of 10^{-6}.

Conclusion: Through the data and information presented, Medtronic Ireland considers the Euphora™ RX Balloon Dilatation Catheter to be substantially equivalent to the predicate device.